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EXAMINER

MITCHELL, GREGORY W

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/557,187
Filing Date: April 21, 2000
Appellant(s): BAKER, AMY E.

Rick Shoop
Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 15, 2004 appealing from the Office action mailed July 18, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. the 35 USC 112, second paragraph, rejection of claims 1, 2, 4, 5, 7-11, 13 and 15-22.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

DE 3,127,590	Kozak (translation provided June 16, 2005)	08-1982
5,976,521	Briggs et al.	11-1999
4,322,020	Stone	03-2000
5,612,324	Guang Lin et al.	03-1997
5,759,559	Fitzjarrel	06-1998

Sciarra, J.J. "Aerosols", Remington: The Science and Practice of Pharmacy, 19th ed., (1995), p. 1682.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak (translation of DE 3127590) in view of both Briggs et al. (USPN 5976521) and Stone (USPN 4322020).

The claimed invention is a composition in the form of a fine mist spray comprising 0.01-20% by weight of the solution having a pH above about 5 and a method of using the composition to treat acne. The phrase in claim 1, "adapted only for administration to non-facial body skin to treat acne or acneform conditions" is a preamble reciting the intended use of the composition and no patentable weight is given thereto. The phrase in the same claim "whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced" is viewed as a property that is necessarily present in a composition comprising salicylic acid which has pH of "above about 5". Absent a showing to the contrary, the same composition taught by the prior art will have the same properties as those instantly claimed.

Kozak teaches that it is well known in the art to formulate a topical composition comprising salicylic acid and additional active ingredients into sprayable form. See abstract. The reference teaches using 0.02-6 g of salicylic acid and resorcinol. The method of treating acne with the prior art composition is taught. See page 3, second to last paragraph.

Kozak fails to teach the pH of the composition and using "fine mist pump spray". The reference also fails to teach an aqueous alcoholic solvent.

Briggs et al. teaches an anti-acne composition comprising salicylic acid (Abstract). To deliver salicylic acid in aqueous solution without the salicylic acid precipitation out of solution, the reference teaches that the salicylic acid is dissolved in aqueous/alcoholic solution (col. 1, line 63-col. 2, line 37). Briggs further teaches that the preferred pH of the final aqueous/alcoholic anti-acne active solution is preferably in

Art Unit: 1617

the range of about 1-7 (col. 3, lines 37-47). Ethyl alcohol is preferred and used in the illustrated formulation for the aqueous phase, which contains salicylic acid (col. 3, lines 1-47; col. 11, lines 35-40).

Stone teaches an invertible fine mist pump sprayer that is useful to dispense cosmetic or pharmaceutical compositions (col. 1, line 9-col. 2, line 65). The reference teaches that pump sprays are preferred over aerosols because of the clogging problem in the aerosol valves and environmental concerns (col. 1, lines 22-35). The reference teaches "the particle size of the spray will vary with the rheology of the liquid being sprayed as well as the orifice size." See col. 5, lines 44-49. It is further disclosed, "the lower viscosity of the liquid and the smaller the orifice size, the smaller the particle size obtained." The reference even teaches that for applying cosmetics, spray particle size of 50-500 microns is desirable (col. 1, lines 18-21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a sprayable topical composition comprising salicylic acid and resorcinol along with water and ethanol because Briggs et al. teaches that such formulations prevent salicylic acid from precipitation. One would have been motivated to prepare said formulation because of an expectation of success in preparing a composition beneficial for topical administration, as taught by Kozak, and wherein the salicylic acid would not precipitate from solution, as taught by Briggs et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a composition with the claimed pH because Briggs et al. teaches that the compositions disclosed therein may have a pH of 1-7. Where the general

conditions are disclosed in the prior art, it is within the routine skill of the art to determine the optimal range.

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce a fine mist pump spray with a spray possessing the desired liquid particle size because (1) Kozak teaches sprayable formulations for topical administration comprising salicylic acid; (2) Stone teaches a fine mist pump sprayer that is useful to dispense cosmetic or pharmaceutical compositions; (3) Stone teaches that the use of a pump spray is beneficial over the use of an aerosol; (4) Stone teaches that the variability of the liquid particle size is a matter of routine formulation; and (5) Stone teaches that the preferred particle size for cosmetic and pharmaceutical formulations is 50-500 microns, a range than encompasses the particle sizes as instantly claimed. One would have been motivated to formulate the composition of the combined references into a fine mist pump spray because of an expectation of success in alleviating clogging and environmental problems, as taught by Stone.

Claims 9 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak, Briggs et al. and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17 and 20 above, and further in view of Guang Lin et al. (USPN 5612324).

Kozak, Briggs et al. and Stone apply as disclosed above. The references fail to teach the use of denatured ethyl alcohol.

Guang Lin et al. teaches an anti-acne composition comprising salicylic acid in aqueous/ethanol carrier. SD (specifically denatured) alcohol is used in the formulation. See Examples.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the SD ethanol as the alcohol vehicle of Briggs et al. because (1) Briggs et al. teaches the use of alcohol and ethanol, generally; and (2) Guang Lin et al. teaches that SD ethanol is also known in the art to be useful in salicylic acid compositions comprising water and alcohol. One would have been motivated to specifically utilize SD ethanol because of an expectation of similar success in preparing a salicylic acid aqueous solution wherein the salicylic acid does not precipitate out of solution because SD ethanol is within the range of alcohols taught, generally, by Briggs et al. to be useful therefor.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak, Briggs et al. and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17 and 20 above, and further in view of Fitzjarrell (USPN 5759559).

Kozak, Briggs et al. and Stone apply as disclosed above. The references fail to specifically teach using salicylic acid as the sole anti-acne ingredient.

Fitzjarrell teaches that salicylic acid is a well-known anti-acne agent used for mild acne (col. 1, lines 17-28; col. 2, lines 28-36).

It would have been obvious to one of ordinary skill at the time of the invention to modify the spray composition of the combined references by using salicylic acid alone

Art Unit: 1617

as the sole active anti-acne ingredient because Fitzjarrel teaches salicylic acid, itself, as being a known anti-acne agent. One would have been motivated by an expectation of success in preparing an mild anti-acne spray composition.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kozak, Briggs et al. and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17 and 20 above, and further in view of Sciarra (Remington: Practice of Science and Pharmacy).

Kozak, Briggs et al. and Stone apply as disclosed above. The references lack a specific teaching of the volume of spray per actuation.

Sciarra teaches that topical aerosols have been used in preparations for the treatment of acne. See p. 1676, 1st par. He also teaches that for topical sprays, particles are produced in the size of from 50-200 microns. See p. 1677, 4th par. The reference further teaches that for a typical metered-dose aerosol delivery system for pharmaceuticals, the size of the chamber can be modified so that about 25-150 μ L of the solution can be delivered per actuation, which meets claim 19. See p. 1688, 6th par.-p. 1689, 1st par.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the anti-acne spray of the combined references by designing the size of the chamber as motivated by Sciarra because of the expectation of successfully adjusting the delivered amount per actuation for a suitable dosage.

(10) Response to Argument

A. The 35 U.S.C. § 112, Second Paragraph, Rejection of Claims 1, 2, 4, 5, 7-11, 13 and 15-22 should be Reversed.

Applicant's arguments regarding the rejection of claims 1, 2, 4, 5, 7-11, 13 and 15-22 under 35 USC 112, second paragraph, are persuasive and said rejection is withdrawn.

B. The 35 U.S.C. § 103 Rejection of Claims 1, 2, 4, 5, 7-11, 13 and 15-20 over Kozak in view of Briggs and Stone should not be Reversed.

Applicant's arguments that Examiner has not failed to establish a *prima facie* case of obviousness is not persuasive for the reasons set forth above and below.

Applicant argues on page 10 of the brief filed December 16, 2004 that Kozak, Briggs and Stone "do not teach or suggest the limitation that the fine mist pump spray is 'adapted only for administration to non-facial body skin,' as recited in claim 1 ..." This argument is not persuasive because it is merely a recitation of the intended use of the claimed invention. An intended use of a claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *If the prior art structure is capable of performing the intended use, then it meets the claim.* In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant application, the phrase "adapted only for administration to non-facial body skin" does not provide any additional limitation to the

composition or characteristic of the spray. Therefore, because it would have been obvious, for the reasons described in the office action filed December 22, 2003, to prepare the spray claimed, the recitation "adapted only for the administration to non-facial body skin" is merely an intended use and no weight is given thereto.

Applicant's arguments on pages 11-12 of the brief filed December 16, 2004 that Kozak, Briggs and Stone that the limitation, 'adapted only for administration to non-facial body skin,' is intended to be limiting because "[i]t is clearly the Applicant's intention that [the] feature be encompassed by claim 1" is unpersuasive because Applicant is only claiming a "fine mist spray" composition. The intended use is not given any weight for the reasons discussed above. It is noted that the limitations in Applicant's brief are all directed to *intended uses* of the composition, e.g. "the spray *will* typically *be* used ...", "the spray *being adapted* for application ...", and instructions not to "*spray* directly on or near your face" (emphasis added).

Applicant's arguments on pages 12-13 of the brief filed December 16, 2004 that Kozak, Briggs and Stone that the limitation, 'adapted only for administration to non-facial body skin,' is intended to be limiting because "it contains structural limitations" are not persuasive. Applicant's arguments are directed to structural limitations that are already present in the claims, namely that the pH be above about 5 and the concentration of salicylic acid is between 0.01% and 20% by weight. Accordingly, a composition with a pH and concentration claimed would have the same properties as those instantly claimed and no further structural limitation is recognized for the phrase, 'adapted only for administration to non-facial body skin.'

Applicant's arguments on pages 12-13 of the brief filed December 16, 2004 that Kozak, Briggs and Stone that the limitation, 'adapted only for administration to non-facial body skin,' is intended to be limiting because "[t]here are necessarily structural differences between devices adapted for administration to *only* non-facial body skin, and devices adapted for administration to both facial and non-facial skin (or just facial skin)" are not persuasive. Applicant argues that such things as drying time must be considered. This is not persuasive because the drying time of the spray is a property of the spray. Applicant argues that adaptations include spray amount, nozzle shape, and spray pattern. These arguments are not persuasive because it is within the routine skill of the art to make such adjustments. For example, Stone et al. teaches that it is known in the art to adjust the orifice size of a spray, Sciarra teaches that it is known in the art to adjust the volume of spray administered, etc. Furthermore, Examiner is uncertain how preparing a spray that is "focused onto a small target skin area and dries quickly" would preclude the application of said spray to the face as would be required by adapted only for non-facial body skin.

Applicant argues on pages 14-16 of the brief filed December 16, 2004 that Kozak, Briggs and Stone lack that the limitation, 'solutions of salicylic acid having a pH above about 5.' This argument is not persuasive.

Applicant argues that because Briggs et al. teaches that the preferred pH of the final solution is preferably of less than about pK_a+1 that Briggs et al. does not teach a pH range of 1-7 for salicylic acid. This argument is not persuasive because the teaching in Briggs et al. that the pH range may be 1-7 is not, itself, conditioned on the

pH of the acid used or the acid used, as Applicant alleges. Indeed, the most preferred range of pH taught to be useful in Briggs et al. is disclosed as 2-4 (col. 3, lines 41-47). The skilled artisan would not understand a teaching of a pH of 2-4 as the most preferred range as precluding the use of a composition having a pH of 1-7. Finally, it is noted that even if Applicant's arguments were to be accepted, it would be Examiner's position that a claim of "above about 5" would be obvious over a teaching of "below about 4" because, e.g., a pH of 4.5 is below "about" 4 and is above "about" 5. Accordingly, even under Applicant's limited view of the teaching of Briggs et al., the claims would be rendered obvious.

Applicant argues on pages 17-19 of the brief filed December 16, 2004 that Kozak, Briggs and Stone lack a teaching of the limitation "whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced." Examiner maintains that this is property of a salicylic acid containing fine mist spray with a pH above 5. Applicant has not shown how Applicant's spray is different from the one rendered obvious by the combined references. Accordingly, it is Examiner's position that Applicant's spray is the same as that rendered obvious by the prior art. A product and its properties are inseparable.

Applicant's arguments on pages 17-19 against the extrinsic evidence of Boettcher et al. are not persuasive. As stated in the office action dated December 22, 2003, the prior art reference, Briggs et al. (US 5976521) teaches an anti-acne composition comprising salicylic acid with a pH of 1-7. Examiner provided extrinsic evidence, Boettcher et al. (US 4287190), in the Office Action dated December 22, 2003

that "the missing descriptive matter is necessarily present in the prior art," see §MPEP 2112, namely that as the pH of Briggs et al. increased from 1 to 7, irritation caused by the salicylic acid would decrease. About two decades prior to Applicant's application, Boettcher et al. disclosed that it was advantageous to increase the pH of salicylic acid to prevent irritation (column 2, lines 42-46). Accordingly, given the length of time that it has been known that an increase in pH will prevent irritation, it is Examiner's position that the missing component (i.e. "whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced") would be recognized by one of ordinary skill in the art as an inherent property of a salicylic acid spray with an increased pH. Applicant's arguments that Boettcher et al. does not specifically mention nasal irritation because Boettcher et al. is directed to a topical composition for administration to the skin are not persuasive because Boettcher et al. teaches what is well known in the art: that acids are irritants. Boettcher et al. further teaches what is also well known in the art: that increasing the pH of an acidic solution is known to reduce the irritation effect of said solution.

Applicant's arguments on pages 19-20 of the brief filed December 16, 2004 that there is no motivation to combine Kozak, Briggs and Stone are not persuasive. It is noted that Kozak and Briggs are of an analogous art, namely that both are directed to compositions comprising salicylic acid for the treatment of acne. Furthermore, Kozak and Stone are of an analogous art because both are directed to cosmetic and/or pharmaceutical sprays. Accordingly, it would have been obvious to combine the cited references. Furthermore, one would have been motivated to combine the cited art

Art Unit: 1617

because of an expectation of success in preparing a spray suitable for the treatment of acne, as taught by Kozak, because Kozak teaches the use of salicylic acid composition for the treatment of acne in the form of a spray, generally. Specifically, one would have been motivated to look to Stone to determine how to formulate said spray and one would have been motivated to look to Briggs et al. to formulate a salicylic acid composition whereby the salicylic acid would not precipitate out of solution.

Applicant argues on pages 20-21 of the brief filed December 16, 2004 that there would have been no motivation to combine Briggs et al. with Kozak and Stone because Briggs et al. is directed to a multiple-phase emulsion, not the spray formulation of Kozak and Stone. This argument is not persuasive because Examiner is not relying on Briggs et al. for the form of administration, but simply to show that it is known in the art to formulate salicylic acid in an aqueous/alcoholic solution in order to prevent precipitation of the active. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Accordingly, it is Examiner's position that a *prima facie* case of obviousness has been established and the 35 USC 103 rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17 and 20 over Kozak, Briggs and Stone should stand.

C. The 35 U.S.C. § 103 Rejection of Claims 9 and 18 over Kozak in view of Briggs, Stone and Guang Lin should not be Reversed.

Applicant argues on pages 22-23 of the brief filed December 16, 2004 that Guang Lin et al. does not remedy the defects of Kozak, Stone and Briggs et al. These arguments are not persuasive because Examiner does not agree that Kozak, Stone and Briggs et al. possess the deficiencies alleged.

Applicant argues on page 23 of the brief filed December 16, 2004 that "Examiner has failed to provide any motivation to combine Guang Lin with Kozak, Bruggs and Stone." This argument is not persuasive because Guan Lin et al. discloses an composition comprising salicylic acid and an aqueous/alcoholic vehicle wherein the alcohol is SD ethanol. Because Briggs et al. teaches the use of "alcohol" general and ethanol, specifically, the skilled artisan would have understood SD ethanol to be interchangeable with the teachings of an alcohol and ethanol of Briggs et al.

Accordingly, it is Examiner's position that a *prima facie* case of obviousness has been established and the 35 USC 103 rejection of claims 9 and 18 over Kozak, Briggs, Stone and Guang Lin should stand.

D. The 35 U.S.C. § 103 Rejection of Claims 21 and 22 over Kozak in view of Briggs, Stone and Fitzjarrell should not be Reversed.

Applicant argues on pages 23-24 of the brief filed December 16, 2004 that Fitzjarrell does not remedy the defects of Kozak, Stone and Briggs et al. These arguments are not persuasive because Examiner does not agree that Kozak, Stone and Briggs et al. possess the deficiencies alleged.

Applicant argues on pages 24-25 of the brief filed December 16, 2004 Fitzjarrell teaches away from the use of salicylic acid for the treatment of acne. This argument is

Art Unit: 1617

not persuasive because Fitzjarrell states that "acne can be treated with diet changes, careful washing and nonprescription lotions containing benzoyl peroxide, topical creams containing *salicylic acid*, or other medications" (col. 1, lines 25-28). Furthermore, Fitzjarrell specifically states, "Often, at best, these treatments reduce the intensity or frequency of acne outbreaks." Such teachings clearly show that salicylic acid is known in the art for treating acne. Applicant's allegation that "examiner is completely ignoring the fact that Fitzjarrell's description of salicylic acid in the background section teaches against using salicylic acid to treat acne in favor of the described combination of topical nicinamide spray and oral supplement" is not persuasive. Simply because Fitzjarrell teaches that the composition disclosed therein may be more effective than the salicylic acid composition would not suggest to the skilled artisan that the prior art compositions were rendered obsolete and useless.

Accordingly, it is Examiner's position that a *prima facie* case of obviousness has been established and the 35 USC 103 rejection of claims 21 and 22 over Kozak, Briggs, Stone and Fitzjarrell should stand.

E. The 35 U.S.C. § 103 Rejection of Claim 19 over Kozak in view of Briggs, Stone and Sciarra should not be Reversed.

Applicant argues on pages 25-26 of the brief filed December 16, 2004 that Sciarra does not remedy the defects of Kozak, Stone and Briggs et al. These arguments are not persuasive because Examiner does not agree that Kozak, Stone and Briggs et al. possess the deficiencies alleged.

Art Unit: 1617

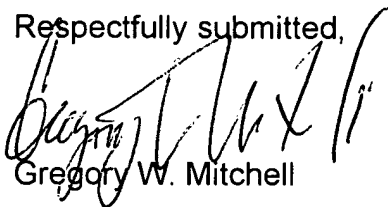
Accordingly, it is Examiner's position that a *prima facie* case of obviousness has been established and the 35 USC 103 rejection of claim 19 over Kozak, Briggs, Stone and Sciarra should stand.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

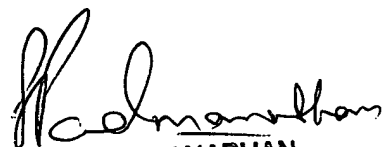
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



Gregory W. Mitchell

Conferees:



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